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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,184	07/16/2003	Eckhard Alt	ACR/050	2237

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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
05/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/622,184	ALT, ECKHARD	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31 and 33-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31 and 33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 23, 2009 has been entered.

Drawings

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the “programmer” in Figure 2 does not have the appropriate sized letters; the elements of Figures 3 and 4 also do not have the appropriately sized lettering denoting the elements; and Figures 6 and 7 contain illegible writing. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

3. Claim 31 is objected to because of the following informalities: In lines 5-6, “at the locality where the impedance measurements are to be performed" should be cancelled from the claim since the language is redundant due to the previous disclosure of

measuring impedance of a portion of the body occupied by the lungs. In line 10, "the trend" lacks antecedent basis in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 33 discloses the method step of: "identifying congestive heart failure as a function of said impedance value and said trend". The current specification fails to support this limitation. At best, the current specification only supports the evaluation of a trend between the heart rate/activity pattern and the concurrent impedance measurement against one another over a selected period of time to provide an indication of congestive heart failure in the patient.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Riff (5,876,353).

Riff discloses an impedance monitor for discerning edema through evaluation of the respiratory rate and further discloses measuring local impedance of a portion of a patient's body generally occupied by the lungs solely through surface mounted electrodes (15a,15b) on the device with the device implanted subcutaneously in the patient's body (Figure 1); determining when the local impedance measurements are indicative of a condition of congestive heart failure based on factors other than the existence of edema (Column 13, lines 59-65); detecting the patient's heart rate or activity pattern through the electrodes while concurrently monitoring the local impedance measurement to evaluate cardiopulmonary status of the patient (Column 5, lines 32-36 and 39-42); evaluating the trend of the heart rate/activity pattern and the concurrent local impedance measurements against one another over a selected period of time, as an additional indicia of congestive heart failure (Column 5, lines 32-36; Column 17, lines 20-23); and determining a trend based on the impedance value and the characteristic of the heart, the trend being indicative of a condition of congestive heart failure (Column 5, lines 32-36; Column 17, lines 20-23).

8. Claims 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Combs et al (5,957,861).

Combs et al disclose an impedance monitor for discerning edema through evaluation of the respiratory rate and further disclose measuring local impedance of a

portion of a patient's body generally occupied by the lungs solely through surface mounted electrodes (15a,15b) on the device with the device implanted subcutaneously in the patient's body (Figure 1); determining when the local impedance measurements are indicative of a condition of congestive heart failure based on factors other than the existence of edema (Column 13, lines 59-65); detecting the patient's heart rate or activity pattern through the electrodes while concurrently monitoring the local impedance measurement to evaluate cardiopulmonary status of the patient (Column 5, lines 32-36 and 39-42); evaluating the trend of the heart rate/activity pattern and the concurrent local impedance measurements against one another over a selected period of time, as an additional indicia of congestive heart failure (Column 5, lines 32-36; Column 17, lines 20-23); and determining a trend based on the impedance value and the characteristic of the heart, the trend being indicative of a condition of congestive heart failure (Column 5, lines 32-36; Column 17, lines 20-23).

Response to Arguments

9. Applicant's arguments with respect to claim 31 have been considered but are moot in view of the new ground(s) of rejection.

Although the claims are rejected under a new grounds of rejection, the rejections are based on the prior art of Combs et al (the specification of Combs et al is the same as the disclosure of Riff). The Examiner would like to respond to the Applicants' arguments regarding the prior art of Combs et al. The Applicants argue: *"Combs et al '861 does not show, disclose or suggest measuring impedance of a portion of the patient's body*

generally occupied by the lungs. While measuring heart or transthoracic impedance is disclosed in various places, neither in the figures or in the specification does Combs et al' 861 disclose measuring lung impedance. Even if Combs et al '861 did show, disclose or suggest measuring lung impedance, Combs et al '861 specifically discloses conducting edema measurements, and does not show, disclose or suggest means for determining congestive heart failure on the basis of factors other than the existence of edema. In addition, Combs et al '861 does not show, disclose or suggest detecting the patient's heart rate/activity pattern and evaluating the trend of the heart rate/activity pattern and lung impedance measurements against one another over a selected period of time as an indicia of congestive heart failure." {emphasis added} The Examiner respectfully disagrees. Combs et al disclose an implanted device in the embodiments of Figures 1 and 6 that measure impedance to detect the presence of edema directly. In order to directly measure edema (the presence of fluid within the lungs), the device must be placed within the region of the lungs; otherwise a measurement of edema cannot be performed. Figure 6 also clearly shows the placement of the implanted device (ID) above the left lung of the patient. Combs et al further discloses in Column 5, lines 8-11, substantial variation can be used for each of the elements of Figures 1 and 2, and still be within the scope of the invention. Therefore the device as shown in Figure 1 can have the additional sensors placed within the implanted device, including sensors for measuring the heart beat cycle, as discussed in Column 5, lines 32-36; the device as shown in Figure 1 can further include the use of the respiratory rate based on the impedance measurement as an indicator of the presence of edema, as discussed in Column 13, lines 59-65 (measuring the respiratory rate using impedance inherently requires the placement of the device in the body at a

location near the patient's lungs); and the device of Figure 1 can further include combining the data from the heart beat cycle with the impedance measurement to provide "additionally beneficial diagnostic data" and "provides an enhanced diagnostic and patient management efficacy" (Column 5, lines 32-36 and Column 13, lines 22-26). The disclosure of Combs et al is clearly directed towards using impedance to detect the presence of edema (an indicator of congestive heart failure) through the evaluation of a patient's respiratory rate (see Title; Abstract, Column 2, lines 37-51, and Column 13, lines 59-65) and using additional sensor data of the heart beat cycle (heart rate) to provide an indicia of congestive heart failure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736